



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

HF1-35

g1031d

WARNING LETTER

19900 MacArthur Blvd., Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7600

March 14, 2001

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

Jenise Luttgens, President
Professional Hospital Supply, Inc.
41980 Winchester Road
Temecula, CA 92590

WL-28-1

Dear Ms. Luttgens:

During inspections of your firm located in Temecula, California, on October 20 to November 3, 2000 and January 31 to February 1, 2001, our investigator determined that your firm manufactures medical device convenience kits. These kits are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act.

Our inspection disclosed that these devices are adulterated within the meaning of Section 510(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, and storage are not in conformance with the Good Manufacturing Practice (GMP) requirements for the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. A process, whose results cannot be fully verified by subsequent inspection and test, has not been validated and approved according to established procedures, as required by 21 CFR.820.75. Specifically, the ethylene oxide sterilization validation and revalidation evaluations conducted by your company do not describe any potential adverse effects of the sterilization process on the products and/or packaging. Our investigation disclosed that the product inserts of several products, including drug products packaged into your medical device convenience kits, display statements advising against elevated temperature exposure, ethylene oxide sterilization, and resterilization. This observation was first brought to your firm's attention during the October 20, 2000 inspection and has not been corrected to date.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

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Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the QS/GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

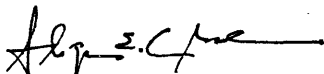
You should take prompt action to correct these deviations. Failure to promptly correct These deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

Sincerely,


Alonza E. Cruse
District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief, Food and Drug Branch
601 North 7th Street, MS-357
Sacramento, CA 94234-7320